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## REMARKS

In the above referenced Office Action, the claims have been rejected under 35 USC 103(a) over Termin et al. ("Termin") in view of Gates et al. ("Gates"). Certain additional references have been further combined with Termin and Gates. Applicant respectfully traverses these rejections.

Applicant respectfully asserts that these rejections are based upon impermissible hindsight and a selective picking and choosing of elements from the references; thus, a failure to consider the references and the claims as whole

As previously stated, Termin provides for the introduction of a shape-memory or self-expanding device into an anatomical structure by advancing that device beyond an introducing sheath or catheter. That is, the catheter is delivered to the target location, the device is pushed out of the catheter and the device either self expands for retention or is heated and then returns to a particular shape. The catheter is then removed and if the device is to be extracted, the catheter is reinserted, over the device and the device is withdrawn into the sheath, causing the device to return to a smaller configuration. (Col. 9, lines 20-25).

Gates teaches an electrical lead having an active fixation electrode that is rotated to cause the electrode to pierce and embed itself within cardiac tissue. As this requires a fair amount of torque, Gates provides for a mechanism by which a stylet is advanced through the body of the electrode and engages a distal portion of the electrode much like a slotted screwdriver. The electrode is then rotated and hence, extended. The use of this mechanism allows higher torque to be applied to the helical electrode through the implanted device (e.g., lead), which remains implanted along with the electrode.

The Examiner asserts that one would be motivated to modify Termin to include the torque delivery mechanism of Gates. The "motivation" would be to provide a "means to easily change the position of the lead without damaging cardiac tissue." Applicant respectfully asserts that this is logically unsupportable,

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fails to provide a legally sufficient motivation to combine references as required by 35 USC 103(a), and demonstrates without question the use of hindsight as the basis for this rejection.

In January of this year, the Court of Appeals for the Federal Circuit squarely addressed this situation.

In making the assessment of differences, section 103 specifically requires consideration of the claimed invention "as a whole." Inventions typically are new combinations of existing principles or features. *Envtl. Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 698 (Fed. Cir. 1983) (noting that "virtually all [inventions] are combinations of old elements."). ***The "as a whole" instruction [\*\*9] in title 35 prevents evaluation of the invention part by part. Without this important requirement, an obviousness assessment might break an invention into its component parts (A + B + C), then find a prior art reference containing A, another containing B, and another containing C, and on that basis alone declare the invention obvious. This form of hindsight reasoning, using the invention as a roadmap to find its prior art components, would discount the value of combining various existing features or principles in a new way to achieve a new result - often the very definition of invention.***

***Section 103 precludes this hindsight discounting of the value of new combinations by requiring assessment of the invention as a whole.*** This court has provided further assurance of an "as a whole" assessment of the invention under § 103 by requiring a showing that an artisan of ordinary skill in the art at the time of invention, confronted by the same problems as the inventor ***and with no knowledge of the claimed invention***, would select the various elements from the prior art and combine them in the claimed manner. ***In other words, the examiner or court must show some suggestion or motivation, before [\*\*10] the invention itself, to make the new combination.*** See *In re Rouffet*, 149 F.3d 1350, 1355- 56 (Fed. Cir. 1998). *Chance v Ruiz*, 357 F.3d 1270; 2004 U.S. App. LEXIS 1325; 69 U.S.P.Q.2D (BNA) 1686 (CAFC 2004) (Emphasis Added)

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The type of analysis criticized appears to be the basis for the present rejection. Namely, the Termin reference illustrates a self-expanding device that, in one embodiment, is helical in shape. The Gates reference is an implanted lead having an extendable, active-fixation helical electrode and a mechanism for applying torque. The Examiner has combined these wholly unrelated references and declared the present claims obvious. In other words, the claimed invention has been broken into its "component parts" A+B, one reference has been found illustrating A, another B and the only basis for the combination is the use of hindsight reasoning and the claims as a "roadmap" for the rejection.

The Termin device is simple in form and function. The self-expanding structures are readily deliverable by extension or retraction of the delivery catheter. Adding a permanent catheter to these devices, then adding a "torque delivery mechanism" to allow for rotation does not, contrary to the Examiner's assertions, provide a means "to easily change the position of the lead." Furthermore, the requirement of adding a permanent catheter (which is absolutely required by the proposed modification) to the Termin device would render it inoperable for its intended purpose in many embodiments. Again, the reference must be considered as a whole; not simply, one Figure taken in isolation.

The particular embodiment relied upon in Termin requires the use of a shape memory metal that is placed into the proper position, then heated to cause the metal to reform into a given shape. The reference indicates that this mechanism is *preferred* (Col. 9, lines 15-18). However, the reference also indicates that the fixation element could be constructed of a self-expanding flexible metal.

Now, if one of ordinary skill in the art chose to provide a *tissue retention structure* to secure fissured tissue after angioplasty (Col. 9, lines 8-11), chose to ignore the preferred embodiment and use self expanding metal, would such an artisan be motivated to incorporate the structure of Gates? The answer is clearly and unambiguously no, and as such, the rejection is unsupportable. Specifically,

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such a combination would require that a catheter be added to the Termin device that remains in place as long as the fixation element is in place (with the combination they are necessarily permanently connected). Since the fixation member is in place to prevent tissue from occluding blood flow after angioplasty, the placement of a larger diameter catheter with the torque generating components of Gates defeats the purpose of the fixation member by occluding blood flow. The Examiner's modification creates the very problem that Termin is attempting to solve.

Applicant respectfully asserts that the rejection of record is insufficient and unsupportable. The pending claims are in condition for allowance and notice of the same is requested. Should any issues remain outstanding, the Examiner is respectfully urged to telephone the undersigned to expedite prosecution.

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# **CONCLUSION**

Finally, if there are any formal matters remaining after this response, the Examiner is requested to telephone the undersigned attorney to attend to these matters.

Respectfully submitted,

Date: 11/15/05



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